

**AMENDMENTS TO THE CLAIMS:**

This listing of claims will replace all prior versions and listings of claims in the application:

1. (Currently amended) An albumin fusion protein comprising a member selected from the group consisting of:
  - (a) ~~a Therapeutic protein:X~~ an interferon alpha protein and albumin, wherein albumin comprises ~~comprising~~ the amino acid sequence of SEQ ID NO:18;
  - ~~(b) a Therapeutic protein:X and a fragment or a variant of the amino acid sequence of SEQ ID NO:18, wherein said fragment or variant has albumin activity;~~
  - ~~(b) (c) a Therapeutic protein:X~~ an interferon alpha protein and a fragment ~~or a variant~~ of the amino acid sequence of SEQ ID NO:18, wherein said fragment ~~or variant~~ has albumin activity, ~~and further wherein said albumin activity is the ability to prolong the shelf life of the Therapeutic protein:X~~ interferon alpha protein compared to the shelf-life of the Therapeutic protein:X interferon alpha protein in an unfused state;
  - ~~(c) (d) a Therapeutic protein:X~~ an interferon alpha protein and a fragment ~~or a variant~~ of the amino acid sequence of SEQ ID NO:18, wherein said fragment ~~or variant~~ has the ability to prolong the shelf-life of the interferon alpha protein compared to the shelf-life of the interferon alpha protein in an unfused state, ~~albumin activity,~~ and further wherein the fragment ~~or variant~~ comprises ~~the amino acid sequence of amino acids~~ amino acid residues 1-387 of SEQ ID NO:18;

(d) [(e)] a ~~fragment or variant of a Therapeutic protein: X~~ an interferon alpha protein and albumin comprising the amino acid sequence of SEQ ID NO:18, wherein said ~~fragment or variant~~ has a biological activity of the interferon alpha protein ~~Therapeutic protein: X~~;

(e) (f) ~~a Therapeutic protein: X~~ an interferon alpha protein, or fragment or variant thereof, and albumin, or fragment or variant thereof, of (a) to [(e)] (d), wherein the interferon alpha protein ~~Therapeutic protein: X~~, or fragment or variant thereof, is fused to the N-terminus of albumin, or the N-terminus of the fragment or variant of albumin;

(f) (g) ~~a Therapeutic protein: X~~ an interferon alpha protein, or fragment or variant thereof, and albumin, or fragment or variant thereof, of (a) to [(e)] (d), wherein the interferon alpha protein ~~Therapeutic protein: X~~, or fragment or variant thereof, is fused to the C-terminus of albumin, or the C-terminus of the fragment or variant of albumin;

(g) (h) ~~a Therapeutic protein: X~~ an interferon alpha protein, or fragment or variant thereof, and albumin, or fragment or variant thereof, of (a) to [(e)] (d), wherein the interferon alpha protein ~~Therapeutic protein: X~~, or fragment or variant thereof, is fused to the N-terminus and C-terminus of albumin, or the N-terminus and the C-terminus of the fragment or variant of albumin;

(h) (i) ~~a Therapeutic protein: X~~ an interferon alpha protein, or fragment or variant thereof, and albumin, or fragment or variant thereof, of (a) to [(e)] (d), which comprises a first interferon alpha protein ~~Therapeutic protein: X~~, or fragment

~~or variant~~ thereof, and a second interferon alpha protein ~~Therapeutic protein:X~~, or fragment ~~or variant~~ thereof, wherein said first interferon alpha protein ~~Therapeutic protein:X~~, or fragment ~~or variant~~ thereof, is different from said second interferon alpha protein ~~Therapeutic protein:X~~, or fragment ~~or variant~~ thereof;

(i) ~~(j)~~ — a ~~Therapeutic protein:X~~ an interferon alpha protein, or fragment ~~or variant~~ thereof, and albumin, or fragment ~~or variant~~ thereof, of (a) to [(i)] (h), wherein the interferon alpha protein ~~Therapeutic protein:X~~, or fragment ~~or variant~~ thereof, is separated from the albumin or the fragment ~~or variant~~ of albumin by a linker; and

(i) ~~(k)~~ — a ~~Therapeutic protein:X~~ an interferon alpha protein, or fragment ~~or variant~~ thereof, and albumin, or fragment ~~or variant~~ thereof, of (a) to [(j)] (i), wherein the albumin fusion protein has the following formula:

R1-L-R2; R2-L-R1; or R1-L-R2-L-R1, and further wherein R1 is interferon alpha protein ~~Therapeutic protein:X~~, or fragment ~~or variant~~ thereof, L is a peptide linker, and R2 is albumin comprising the amino acid sequence of SEQ ID NO: 18 or a fragment ~~or variant~~ of albumin.

2. (Currently amended) The albumin fusion protein of claim 1, wherein the shelf-life of the albumin fusion protein is greater than the shelf-life of the interferon alpha protein ~~Therapeutic protein:X~~, or fragment ~~or variant~~ thereof, in an unfused state.

3. (Currently amended) The albumin fusion protein of claim 1, wherein the in vitro biological activity of the interferon alpha protein ~~Therapeutic protein:X~~, or fragment ~~or variant~~ thereof, fused to albumin, or fragment ~~or variant~~ thereof, is greater than the in

vitro biological activity of the interferon alpha protein ~~Therapeutic protein:X~~, or fragment ~~or variant~~ thereof, in an unfused state.

4. (Currently amended) The albumin fusion protein of claim 1, wherein the in vivo biological activity of the interferon alpha protein ~~Therapeutic protein:X~~, or fragment ~~or variant~~ thereof, fused to albumin, or fragment ~~or variant~~ thereof, is greater than the in vivo biological activity of the interferon alpha protein ~~Therapeutic protein:X~~, or fragment ~~or variant~~ thereof, in an unfused state.

5. An albumin fusion protein comprising a ~~peptide~~ an interferon alpha protein or fragment thereof, inserted into an albumin, or fragment ~~or variant~~ thereof, comprising the amino acid sequence of SEQ ID NO:18 or fragment ~~or variant~~ thereof.

6. An albumin fusion protein comprising a ~~peptide~~ an interferon alpha protein or fragment thereof, inserted into an albumin, or fragment ~~or variant~~ thereof comprising an amino acid sequence selected from the group consisting of:

- (a) ~~amino acids~~ amino acid residues 54 to 61 of SEQ ID NO:18;
- (b) ~~amino acids~~ amino acid residues 76 to 89 of SEQ ID NO:18;
- (c) ~~amino acids~~ amino acid residues 92 to 100 of SEQ ID NO:18;
- (d) ~~amino acids~~ amino acid residues 170 to 176 of SEQ ID NO:18;
- (e) ~~amino acids~~ amino acid residues 247 to 252 of SEQ ID NO:18;
- (f) ~~amino acids~~ amino acid residues 266 to 277 of SEQ ID NO:18;
- (g) ~~amino acids~~ amino acid residues 280 to 288 of SEQ ID NO:18;
- (h) ~~amino acids~~ amino acid residues 362 to 368 of SEQ ID NO:18;

- (i) ~~amino-acids~~ amino acid residues 439 to 447 of SEQ ID NO:18;
- (j) ~~amino-acids~~ amino acid residues 462 to 475 of SEQ ID NO:18;
- (k) ~~amino-acids~~ amino acid residues 478 to 486 of SEQ ID NO:18; and
- (l) ~~amino-acids~~ amino acid residues 560 to 566 of SEQ ID NO:18.

7. The albumin fusion protein of claim 5, wherein said albumin fusion protein comprises a ~~portion~~ fragment of albumin sufficient to prolong the shelf-life of the ~~peptide interferon alpha protein or fragment thereof~~, as compared to the shelf-life of the ~~peptide interferon alpha protein or fragment thereof~~, in an unfused state.

8. The albumin fusion protein of claim 6, wherein said albumin fusion protein comprises a ~~portion~~ fragment of albumin sufficient to prolong the shelf-life of the ~~peptide interferon alpha protein or fragment thereof~~, as compared to the shelf-life of the ~~peptide interferon alpha protein or fragment thereof~~, in an unfused state.

9. The albumin fusion protein of claim 5, wherein said albumin fusion protein comprises a ~~portion~~ fragment of albumin sufficient to prolong the in vitro biological activity of the ~~peptide interferon alpha protein or fragment thereof~~, fused to albumin as compared to the in vitro biological activity of the ~~peptide interferon alpha protein or fragment thereof~~, in an unfused state.

10. The albumin fusion protein of claim 6, wherein said albumin fusion protein comprises a ~~portion~~ fragment of albumin sufficient to prolong the in vitro biological activity of the ~~peptide interferon alpha protein or fragment thereof~~, fused to albumin as

compared to the in vitro biological activity of the peptide interferon alpha protein or fragment thereof, in an unfused state.

11. The albumin fusion protein of claim 5 wherein said albumin fusion protein comprises a ~~portion~~ fragment of albumin sufficient to prolong the in vivo biological activity of the peptide interferon alpha protein or fragment thereof, fused to albumin compared to the in vivo biological activity of the peptide interferon alpha protein or fragment thereof, in an unfused state.

12. The albumin fusion protein of claim 6 wherein said albumin fusion protein comprises a ~~portion~~ fragment of albumin sufficient to prolong the in vivo biological activity of the peptide interferon alpha protein or fragment thereof, fused to albumin compared to the in vivo biological activity of the peptide interferon alpha protein or fragment thereof, in an unfused state.

13. (Original) The albumin fusion protein of any one of claims 1-12, which is nonglycosylated.

14. (Original) The albumin fusion protein of any one of claims 1-12, which is expressed in yeast.

15. (Original) The albumin fusion protein of claim 14, wherein the yeast is glycosylation deficient.

16. (Original) The albumin fusion protein of claim 14 wherein the yeast is glycosylation and protease deficient.

17. (Original) The albumin fusion protein of any one of claims 1-12, which is expressed by a mammalian cell.

18. (Original) The albumin fusion protein of any one of claims 1-12, wherein the albumin fusion protein is expressed by a mammalian cell in culture.

19. (Original) The albumin fusion protein of any one of claims 1-12, wherein the albumin fusion protein further comprises a secretion leader sequence.

20. (Original) A composition comprising the albumin fusion protein of any one of claims 1-12 and a pharmaceutically acceptable carrier.

21. (Original) A kit comprising the composition of claim 20.

22. (Withdrawn) A method of treating a disease or disorder in a patient, comprising the step of administering the albumin fusion protein of any one of claims 1-12.

23. (Withdrawn) The method of claim 22, wherein the disease or disorder comprises indication:Y.

24. (Withdrawn) A method of treating a patient with a disease or disorder that is modulated by Therapeutic protein:X, or fragment or variant thereof, comprising the step of administering an effective amount of the albumin fusion protein of any one of claims 1-12.

25. (Withdrawn) The method of claim 24, wherein the disease or disorder is indication:Y.

26. (Currently Amended) A method of extending the shelf life of an interferon alpha protein ~~Therapeutic protein:X~~, or fragment or variant thereof, comprising the step of fusing the interferon alpha protein ~~Therapeutic protein:X~~, or fragment or variant thereof, to albumin, or fragment or variant thereof, sufficient to extend the shelf-life of the interferon alpha protein ~~Therapeutic protein:X~~, or fragment or variant thereof, compared to the shelf-life of the interferon alpha protein ~~Therapeutic protein:X~~, or fragment or variant thereof, in an unfused state.

27. (Original) A nucleic acid molecule comprising a polynucleotide sequence encoding the albumin fusion protein of any one of claims 1-12.

28. (Original) A vector comprising the nucleic acid molecule of claim 27.

29. (Original) A host cell comprising the nucleic acid molecule of claim 28.

30-50. (Canceled)

51. (Withdrawn) A method of treating a disease or disorder in a patient, comprising the step of administering the albumin fusion protein of any one of claims 30-41.

52. (Withdrawn) The method of claim 51, wherein the disease or disorder comprises a member selected from the group consisting of: Hairy cell leukemia;



Kaposi's sarcoma; genital warts; anal warts; chronic hepatitis B; chronic non-A, non-B hepatitis; hepatitis C; hepatitis D; chronic myelogenous leukemia; renal cell carcinoma; bladder carcinoma; ovarian carcinoma; cervical carcinoma; skin cancer; recurrent respirator papillomatosis; non-Hodgkin's lymphoma; cutaneous T-cell lymphoma; melanoma; multiple myeloma; AIDS; multiple sclerosis; and glioblastoma.

53. (Withdrawn) A method of treating a patient with a disease or disorder that is modulated by interferon-alpha, or fragment or variant thereof, comprising the step of administering an effective amount of the albumin fusion protein of any one of claims 30-41.

54. (Withdrawn) The method of claim 53, wherein the disease or disorder comprises a member selected from the group consisting of: Hairy cell leukemia; Kaposi's sarcoma; genital warts; anal warts; chronic hepatitis B; chronic non-A, non-B hepatitis; hepatitis C; hepatitis D; chronic myelogenous leukemia; renal cell carcinoma; bladder carcinoma; ovarian carcinoma; cervical carcinoma; skin cancer; recurrent respirator papillomatosis; non-Hodgkin's lymphoma; cutaneous T-cell lymphoma; melanoma; multiple myeloma; AIDS; multiple sclerosis; and glioblastoma.

55. (Withdrawn) A method of extending the shelf life of interferon-alpha, or fragment or variant thereof, comprising the step of fusing the interferon-alpha, or fragment or variant thereof, to albumin, or fragment or variant thereof, sufficient to extend the shelf-life of the interferon-alpha, or fragment or variant thereof, compared to the shelf-life of the interferon-alpha, or fragment or variant thereof, in an unfused state.

56. (Withdrawn) A nucleic acid molecule comprising a polynucleotide sequence encoding the albumin fusion protein of any one of claims 30-41.
57. (Withdrawn) A vector comprising the nucleic acid molecule of claim 56.
58. (Withdrawn) A host cell comprising the nucleic acid molecule of claim 57.
59. (Withdrawn) An albumin fusion protein comprising albumin, or a fragment or variant thereof, and a protein selected from the group consisting of:
- (a) serum cholinesterase;
  - (b) alpha-1 antitrypsin;
  - (c) aprotinin;
  - (d) coagulation complex;
  - (e) von Willebrand factor;
  - (f) fibrinogen;
  - (g) factor VII;
  - (h) factor VIIA activated factor;
  - (i) factor VIII;
  - (j) factor IX;
  - (k) factor X;
  - (l) factor XIII;
  - (m) C1 inactivator;
  - (n) antithrombin III;
  - (o) thrombin;

- (p) prothrombin;
- (q) apo-lipoprotein;
- (r) c-reactive protein;
- (s) protein C; and
- (t) immunoglobulin.

60. (Canceled).